

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	PLICATION NO. FILING DATE 09/890,425 02/19/2002		FIRST NAMED INVENTOR  Harold G. Brown	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,425				2059-0103P	1812
2292	7590 02/15/2005			EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747				PRATS, FRANC	SCO CHANDLER
FALLS CHURCH, VA 22040-0747				ART UNIT	PAPER NUMBER
	,			1651	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
09/890,425	BROWN ET AL.	
Examiner	Art Unit	

**Advisory Action** Before the Filing of an Appeal Brief --The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 31 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. X The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires 4 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b), ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. X The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below): (b) They raise the issue of new matter (see NOTE below): (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 2,6,7,11,12,14,19,22,23,36-38,41,42,46-51,53,54,59,66,69-95,112-115,117 and 118. Claim(s) withdrawn from consideration: 3,8,9,13,24-27,30-35,52,60,63-65,67,96-111 and 116. AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER

11. 

The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s

13. Other: \_\_\_\_.

Primary/Examiner Art Unit: 1651

## **Continuation Sheet (PTO-303)**

Continuation of 3. NOTE: The new language requiring monkey eye and horse joint reactions and also requiring the absence of reactions upon skin, oral and mucosal application has not been searched or considered previously. Thus, the new limitation must be considered not only with respect to the prior art, but also with respect to support in the application as filed. Also, the insertion of molecular weight ranges requires additional consideration because it is not clear that embodiments comprising all of the present limitations were searched or considered previously.

Continuation of 11. does NOT place the application in condition for allowance because: All of applicant's argument regarding the 102 rejections assumes entry of the non-entered amendment, and therefore cannot be considered persuasive, since said argument addresses a limitation not present in the claims. Moreover, even if the amendment were entered, applicant does not supply actual evidence in support of the assertion that any of the prior art hyaluronic acid lacks the newly claimed property. In this regard, it is respectfully pointed out that the hyaluronic acid used by applicant in the specification is from a commercial source. It is therefore unclear how the product can be any different than that disclosed in any of the prior art. Moreover, the language "causes reactions" encompasses any sort of measurable reaction, and would appear to encompass any administration of hyaluronic acid to monkey eyes or horse joints, even favorable ones.

With respect to the issue of obviousness, as discussed above, even if the amendment at issue were entered, the language "causes reactions" encompasses any sort of measurable reaction, even a favorable one, and would appear to encompass any administration of hyaluronic acid to monkey eyes or horse joints. Also, as pointed out above, applicant fails to support the argued lack of "reaction" with any objective evidence. Moreover, only one of several suitable hyaluronic acid preparations is disclosed by Turley as passing the rabbit ocular test. Thus, applicant's argument ignores the fact that Turley discloses that a number of different hyaluronate preparations having different degrees of purity are disclosed by Turley as being suitable for use in accordance therein, and the fact that "reaction" encompasses any reaction, including a favorable one.

With respect to Turley's enablement, it is respectfully pointed out that the claims under examination are directed to compositions, and Turley cleary suggests orally acceptable compositions. With respect to suitable molecular weight fractions, it is respectfully pointed that, even if the amendment at issued were entered, a significant number of applicant's claims would lack any sort of molecular weight requirement. Moreover, those claims containing a molecular weight limitation could be considered obvious in view of Turley's extremely broad suitability range of molecular weights. See page 5, lines 18-31. As to the use of all of the claimed vehicles, it is respectfully submitted that the use of any known orally acceptable vehicle would be obvious in view of Turley's disclosure of the suitability of oral administration. No hindsight is required for such a conclusion.